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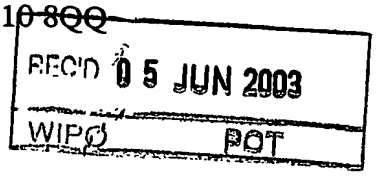

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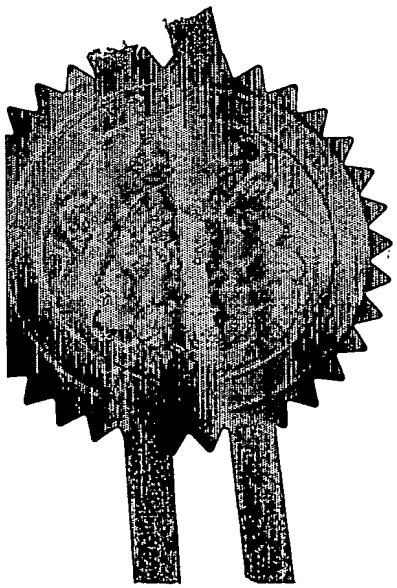

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Dated 19 May 2003

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1. Your reference — AFB/MJE/P8944GB

2. Patent application number
(The Patent Office will fill in this part) — 0210023.8

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

AIR PRODUCTS AND CHEMICALS, INC.
7201 Hamilton Boulevard
Allentown
Pennsylvania 18195-1501
USA

Patents ADP number *(if you know it)* 55583660001

If the applicant is a corporate body, give the country/state of its incorporation — USA (Delaware)

4. Title of the invention — MEDICAL GAS RECIRCULATION SYSTEM

5. Name of your agent *(if you have one)* — W. H. Beck, Greener & Co.

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

W. H. Beck, Greener & Co.
7 Stone Buildings
Lincoln's Inn
London WC2A 3SZ

Patents ADP number *(if you know it)* — 323001 ✓

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
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Description	18
Claim *(s)*	9
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Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
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11. I/We request the grant of a patent on the basis of this application.

Signature W.H. Beck, Greener & Co Date 01.05.02

12. Name and daytime telephone number of person to contact in the United Kingdom: Mr. Michael Ellis - (020) 7405 0921

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Medical Gas Recirculation System

The present invention relates to an apparatus and method for recirculating at least a binary gas mixture to a medical device such as a cardiac pulmonary bypass oxygenator or an artificial ventilator.

More particularly the invention relates to an apparatus and method for controlling the composition, pressure and flow rate of a recirculating gaseous composition to a medical device, particularly to a cardiopulmonary bypass oxygenator, and recycling the gaseous composition.

Medical devices such as cardiopulmonary bypass oxygenators and artificial ventilators or respirators require a reliable and constant source of gas for safe and reliable operation for use during the relevant medical procedures.

Usually, the gaseous compositions used for procedures with such devices are various air/oxygen or nitrogen/oxygen mixtures, although in some situations, these devices may be used for administering other active agents to a patient.

For example, it is common to use a respirator for administering an anaesthetic agent to anaesthetise a patient prior to undergoing certain surgical procedures. Xenon is known for use as an anaesthetic agent.

US-A-4989597 (Werner) discloses an apparatus for administration of at least two gases, particularly oxygen and xenon, to a patient via a respiration apparatus comprising a patient circuit and a drive circuit. The patient circuit, which enables rebreathing of the gas to make maximal use of valuable gases, is provided with fresh gas input to replace exhaled carbon dioxide with oxygen and to supplement the xenon concentration. The drive circuit

and the patient circuit are in open communication and the concentration of each of the components in the patient circuit is independently monitored and controlled by addition of small quantities of one or other of the gases. The open communication between the patient circuit and the drive circuit results in an inherent equilibrium which it is stated allows the relative concentration of gases in the patient circuit to be more controllable. Xenon eventually accumulates in the drive circuit and can be recovered therefrom by supply to a recovery bottle once a certain concentration has been reached.

More recently, xenon has been identified as being useful in the treatment of neurointoxications, for example in WO-A-0053192 (AGA et al). In particular, it is stated that xenon can reduce the release of neurotransmitters, particularly dopamine, which is caused by, for example, hypoxic situations such as an apoplexy or a craniocerebral trauma. It is stated (on page 5, lines 15-18 of WO-A-0053192) that use of the cardiopulmonary bypass machine can cause an unidentified neurointoxication, which significantly delays a patient's reconvalescence. According to WO-A-0053192, xenon may be administered by an inhalation method, or alternatively, may be added directly to a cardiopulmonary bypass machine.

Under normal circumstances, cardiopulmonary bypass oxygenators are supplied with an oxygen/air or oxygen/nitrogen mixture on a once-through basis after which the spent gas (comprising the remaining oxygen, nitrogen and carbon dioxide flushed from the patient's blood) is vented to atmosphere. However, the use of xenon, or any other high value gas, in a cardiopulmonary bypass oxygenator would make this a very expensive procedure.

An apparatus and method for providing and recirculating gas to a medical device, such as a cardiopulmonary bypass

oxygenator or an artificial ventilator, which also enables recovery of the high value gas is highly desirable, particularly when applied to a medical device used in an environment where space is at a premium.

Accordingly, in a first aspect of the invention there is provided an apparatus comprising:-

a medical device requiring a supply of a gaseous composition comprising a first gas and a second gas;

a main circuit for recirculating gas through the medical device and comprising:-

a circulation pump for pumping gas through the main circuit,

a gas outlet connected to the medical device,

a gas inlet connected to the medical device,

a first supply conduit for supply of gas of a first composition to the main circuit,

a second supply conduit for supply of gas of a second composition different from said first composition to the main circuit,

a first supply flow control means for controlling the flow of gas through the first supply conduit, and

a second supply flow control means for controlling the flow of gas through the second supply conduit;

a concentration determining means for determining the concentration of at least one gas of the gaseous composition within the main circuit; and

a means for venting gas from the main circuit.

Preferably, the apparatus includes a bypass conduit, which permits at least a portion of the recirculating gas to bypass the gas outlet, the medical device and the gas inlet. The apparatus may also include a gas outlet flow control

means, for example a valve, for controlling the flow through the gas outlet to the medical device.

In a preferred embodiment, there is provided a pressure maintaining means for maintaining the pressure to the gas outlet by controlling the flow of gas through the bypass conduit, for example, by use of a valve, whereby flow of gas through the bypass conduit is prevented unless a predetermined pressure, for example 30 millibar gauge (mbarg) (103 kPa absolute), is attained. The pressure will then be maintained upstream from the bypass conduit and thus also upstream from the gas outlet to the medical device at around the predetermined pressure, so that a setting on the gas outlet flow controller enables a constant flow of gas to the medical device.

In addition to, or instead of, the bypass flow control means, there may be provided a circuit volume regulating means for taking up temporary increases in recirculating gas volume and compensating for temporary decreases in recirculating gas volume. Preferably, said means is in the form of expansion bellows or the like. Preferably, there is also a monitoring means for monitoring the degree of variation of the volume of recirculating gas. The monitoring means may be an ultrasonic or infra-red level sensor for detecting the level of the expansion bellows in an expandable direction thereof, but is preferably and ultrasonic level sensor.

The apparatus preferably operates at a pressure of up to about 250 mbarg (125 kPa) through the bypass circuit, more preferably up to about 150 mbarg (115 kPa) and may provide gas to the medical device at a pressure of up to about 100 mbarg (110 kPa), but preferably about 30 mbarg (103 kPa). The circulation pump may circulate gas through the circuit at a rate of up to about 80 litres per minute (l/min), preferably up to about 30 l/min, more preferably

from about 15 to about 20 l/min and preferably supplies gas to the medical device at a rate of up to about 30 l/min, preferably up to about 10 l/min and still more preferably up to about 5 l/min.

Each of the first and second supply flow control means may be, for example, a valve or, preferably, a mass flow controller (MFC).

There may be one or more concentration determining means and typically, the or each concentration determining means will be dedicated for analysis of a single component of the gas mixture. Preferably, the or each concentration determining means communicates with supply flow control means for controlling the supply of a respective gas, such that when the composition of the gas is found to exceed or fall below, as appropriate, a predetermined level or concentration, the supply flow control means is triggered to alter the flow rate of gas to the main circuit. For example, a minimum concentration of a first gas in the gaseous composition circulating through the apparatus may be desired and the analyser or other gas concentration determining means may be set by the operator to send a signal to trigger the relevant supply flow control means when the measured concentration falls below the desired concentration such that the flow of that gas into the circuit is increased, thereby increasing the concentration of that gas in circulation. Alternatively, the gas concentration determining means can provide a signal to alert the operator, for example, by way of an alarm, to the need to manually adjust the relevant supply flow control means.

The monitoring means for the circuit volume regulating means may communicate with the relevant supply flow control means, such that when, for example, the monitor indicates that the volume of gas in the circuit has fallen below a

predetermined minimum level, a selected supply flow control means is triggered to alter the flow rate of gas to the main circuit to return the volume to the desired level. Depending upon which supply flow control means is selected and upon the composition of gas supplied through the selected supply conduit, the concentration of gases in the circuit may thereby be affected and/or controlled.

Communication of the concentration determining means or volume monitoring means with the supply flow control means may be via an analog electrical circuit, on which the gain may be set as desired. For example, for control of a supply of a gas which is rapidly consumed and/or urgently required by the medical device, the analog circuit may have a high gain. Conversely, for control of a supply of a relatively slowly consumed gas the analog circuit may have a low gain.

Preferably the medical device is a cardiopulmonary bypass oxygenator or an artificial ventilator. The apparatus is particularly applicable to use with a cardiopulmonary bypass oxygenator.

In a second aspect of the present invention, there is provided an apparatus for providing and circulating a gaseous composition to a medical device, said apparatus comprising:-

a main circuit for recirculating gas to the medical device and comprising:-

a circulation pump for pumping gas through the main circuit to supply the medical device with a gas composition comprising a first gas and a second gas,

a gas outlet for connection to the medical device to supply gas thereto,

a gas inlet for connection to the medical device to receive spent gas therefrom,

a first supply conduit for supply of gas of a

first composition to the main circuit,

a second supply conduit for supply of gas of a second composition different from said first composition to the main circuit,

a first supply flow control means for controlling the flow of gas through the first supply conduit, and

a second supply flow control means for controlling the flow of gas through the second supply conduit;

a concentration determining means for determining the concentration of at least one gas of the gaseous composition within the main circuit; and

a means for venting gas from the circuit.

In a third aspect of the invention there is provided a method of providing a medical device with a gaseous composition comprising a first gas and a second gas, said method comprising:-

feeding a gaseous composition of a desired composition to the medical device;

collecting spent gas mixture from the device,

determining the concentration of each of the components of the gaseous composition remaining in the spent gas mixture;

processing the spent gas mixture to remove unwanted components;

replenishing components in the spent gas mixture in response to the concentration determination to regenerate said desired composition; and

recirculating the resultant gaseous composition to the medical device.

Preferably, the pressure of the gaseous composition being fed to the medical device is maintained at a desired level by diverting a portion of the gaseous composition to bypass the medical device when the desired pressure is exceeded.

The spent gas may be removed and stored for later recovery in response to the concentration determination should the concentration of an active component in the mixture fall below predetermined level or an unwanted contaminant exceed a predetermined level.

Preferably, any or all of the replenishment and the removal steps can be carried out automatically in response to the concentration determination.

The medical device may be, for example, a cardiopulmonary bypass oxygenator or an artificial ventilator. The method is particularly applicable to provision of gas to a cardiopulmonary bypass oxygenator.

In a fourth aspect of the invention, there is provided a method for the extracorporeal treatment of blood by contacting blood with a recirculating gaseous composition in a device provided with a gaseous composition using the method defined above.

The gaseous composition for use in the present invention preferably contains at least one high value gas, which it would be beneficial to recover after use in the process. Such gases include the noble gases, especially xenon, krypton and neon or isotopes thereof, or stable isotopes of gases such as oxygen and carbon dioxide.

In a preferred embodiment, the gaseous composition comprises xenon, preferably in an amount of at least about 10% by volume, more preferably at least about 30%, still

more preferably at least about 50% and still more preferably at least about 70% by volume. Most preferably, the gaseous composition comprises xenon in an amount of about 80% by volume.

The gaseous composition preferably also comprises oxygen and more preferably consists predominantly of xenon and oxygen. Most preferably, the gaseous composition comprises xenon and oxygen in a ratio of about 80% to about 20% by volume and usually will consist solely of xenon and oxygen.

The component gases may be replenished individually or in a mixture of gases, preferably a binary mixture, of known relative proportions.

Optionally, the gaseous composition may also comprise, for example, helium or nitrogen. Helium may be provide through a further supply flow conduit from, for example, a helium cylinder or a cylinder containing a helium/oxygen mixture. Nitrogen may be provided, for example, by admitting air to the circuit.

In a preferred embodiment of the invention, the medical device is a cardiopulmonary bypass oxygenator and the gaseous composition is a mixture predominantly of oxygen and xenon. Preferably the component gases are supplied from a first gaseous supply comprising oxygen and a second gaseous supply comprising xenon, which may be a xenon/oxygen mixture, for example in a ratio of about 80% to about 20%. Preferably the first gaseous supply is oxygen and the second gaseous supply is a xenon/oxygen mixture.

When oxygen is relatively quickly consumed, by a patient connected to the medical device, the oxygen concentration determining means, which may be, for example, an oxygen fuel cell sensor, preferably is connected to the

first supply flow control means by a high gain electronic circuit enabling relatively rapid replenishment of oxygen to the circuit. For example, every 1% difference between the desired concentration and the detected concentration of oxygen may correspond to a flow through the oxygen (first) supply conduit of 1 litre per minute (l/min). Conversely, for means for controlling the concentration of xenon, which is relatively slowly consumed by a patient connected to the medical device, a low gain response may be more appropriate.

It is preferred that the concentration of xenon in a recirculating binary mixture with oxygen is determined with an ultrasonic gas analyser. Preferably, the ultrasonic gas analyser has an ultrahigh frequency ultrasonic transmitter, for example greater than 100 kHz. A suitable ultrasonic gas analyser is that described in our co-pending application of even date (file reference: P8942GB).

The ultrasonic gas analyser may be used in combination with monitoring the recirculating volume to provide other information such as the concentration of contaminants in the circuit.

Similarly, comparison of the measured concentration of oxygen and xenon, in the recirculating gas, may provide information on the concentration of contaminants such as nitrogen or carbon dioxide.

When xenon or other high value gases are used, it is preferable to direct spent or recirculating gas that may from time to time be vented into a gas recovery space. Where the high value gas is provided from a supply in a fresh gas space in a container having an ullage space, the ullage space may provide the gas recovery space. Such a container can be as described in our co-pending application of even date (file reference: P8943GB).

One or more of a carbon dioxide absorber, a carbon dioxide analyser and a pressure relief device can be provided downstream from the medical device when carbon dioxide is a waste product from that device.

The following is a description by way of example only and with reference to the accompanying drawings of presently preferred embodiments of the invention. In the drawings:

Figure 1 is a diagramatical representation of an apparatus according to the present invention for providing a xenon/oxygen mixture to a cardiopulmonary bypass oxygenator;

Figure 2 is a diagramatical representation of a ventilator circuit for introduction into the apparatus of Figure 1 to replace the cardiopulmonary bypass oxygenator; and

Figure 3 is a diagramatical representation of another ventilator circuit for introduction into the apparatus of Figure 1 to replace the cardiopulmonary bypass oxygenator.

With reference to Figure 1, xenon/oxygen mixture in a ratio of 80% xenon to 20% oxygen is fed into the main circuit 102 of the apparatus (generally designated 101) from a xenon/oxygen supply in fresh gas space 119 of container 121 via xenon mass flow controller (MFC) 123.

The oxygen content of main circuit 102 may be topped up from oxygen cylinder 125 via regulator 127 and oxygen mass flow controller (MFC) 129.

One or more (preferably four) diaphragm pumps 117 pump the xenon/oxygen mixture around the circuit 102 at a rate of up to 20 litres per minute (l/min) at a pressure of up to 150 millibar gauge (1150 kPa).

The gaseous composition is fed to cardiopulmonary bypass (CPB) oxygenator 103 via gas outlet 105, which is

regulated by flow control valve 139, which may be set at a desired level by the operator.

CPB oxygenator 103, which is typically a membrane oxygenator, is fed unoxygenated blood from a patient 107 via unoxygenated blood conduit 109 and returned to the patient 107 via oxygenated blood conduit 111. Spent gas from the CPB oxygenator 103 is fed through gas inlet 113 and then through water trap 147, primary carbon dioxide absorber 135 and pump(s) 117.

Gas passing through the inlet 113 and outlet 105 pass through respective bacterial filters 115 to protect the patient 107 from contamination from the apparatus 101 and vice versa.

In order to ensure that a constant flow of gas at the set pressure is supplied to the oxygenator 103 and thus available to the patient's blood, excess gas is fed through bypass conduit 140 via pressure maintaining valve 141 upstream from the flow control valve 139. Pressure maintaining valve 141 is a valve which allows gas flow through the bypass conduit 140 only when the pressure exceeds a predetermined level, for example 30 mbarg (103 kPa).

Downstream from the pressure maintaining valve 141, the gaseous composition is analysed for xenon content using ultrasonic xenon analyser 143 of the kind described in our copending patent application of even date (file reference P8942GB). The gas is then fed via bellows 145, which expand to take up any additional volume of gas in the apparatus or contract to compensate for loss of volume in the apparatus, and rejoins the main circuit 102 upstream of pump(s) 117.

The oxygen concentration in the main circuit 102 is monitored by oxygen fuel cell sensor 131 situated in the

main circuit 102 downstream from pump(s) 117. The gas is then fed through backup carbon dioxide absorber 133, which removes residual carbon dioxide from the recirculating gas. The carbon dioxide removed by absorbers 133 and 135 has entered via the oxygenator 103 after being flushed from the patient's blood. At least absorber 135 should be replaced with each use of the system.

Downstream from the backup carbon dioxide absorber 135, a small sample of gas is drawn from the main circuit and fed to analyser unit 137 to be analysed for carbon dioxide, via an infra red gas analyser, to ensure that the carbon dioxide absorbers are working efficiently and for oxygen, via a paramagnetic gas analyser, as a backup to the oxygen fuel cell sensor 131. The sample is returned to the main circuit upstream from the pump(s) 117.

Recovery gas conduit 149 feeds spent gas from the main circuit 102 at a point downstream from the backup carbon dioxide absorber 135 to the ullage space 151 of container 121, via recovery valve 153 and compressor 155. This container 121 is of the kind described in our copending patent application of even date (file reference P8943GB).

An atmospheric vent 157 from bellows 145 enables the gas within the apparatus to be vented to atmosphere if desired.

There is a U-tube relief device 159 on the gas inlet 113 to protect the oxygenator 103 and patient 107 in the event of any back pressure from the apparatus 101.

Addition of fresh gas to the apparatus is controlled by an analog electronic circuit (not shown) between oxygen fuel cell sensor 131 and oxygen MFC 129 for fresh oxygen addition and by an analog electronic circuit between an ultrasonic level sensor 146 measuring the position of the bellows and

the xenon MFC 123 for fresh xenon/oxygen mixture addition.

As well as monitoring the concentration of oxygen in the main circuit 102, oxygen fuel cell sensor 131 enables the oxygen concentration to be controlled. The operator may choose a set point on the sensor 131 corresponding to the desired oxygen concentration. If oxygen concentration measured by sensor 131 falls below the set point, oxygen MFC 129 is triggered to feed fresh oxygen into the main circuit 102 at a rate proportional to the difference between the oxygen level set point and the oxygen sensor 131 measurement via the high gain circuit connecting oxygen MFC 129 to sensor 131.

Typically, the high gain oxygen control circuit (not shown) will have a gain of 1, corresponding to an oxygen flow rate through oxygen MFC 129 and into the main circuit 102 of 1 l/min for every 1% difference between the oxygen set point and the measured oxygen level.

The xenon concentration of the main circuit is controlled by ultrasonic bellows level sensor 146. The operator may set the desired level on a potentiometer (not shown) which is connected to sensor 146, which corresponds to an expanded level of the bellows 145. This level corresponds to the volume in the system and, given that the oxygen concentration is known, to a desired concentration of xenon. When the sensor 146 detects that the bellows 145 has fallen below the desired level, xenon MFC 123 is triggered to feed fresh oxygen/xenon mixture into the main circuit 102 at a rate proportional to the difference between the potentiometer set point and the level measured by bellows sensor 146, via the low gain circuit (not shown) connecting sensor 146 to xenon MFC 123.

Typically, the xenon low gain circuit will have a gain of 0.1, corresponding to a flow of fresh xenon/oxygen

mixture into the main circuit 102 of 0.1 l/min for every 1% difference between the potentiometer setpoint and the level measured by bellows sensor 146.

The various sensor readings and flow rates are displayed on a monitoring unit (not shown).

In use, oxygen is consumed and replaced by carbon dioxide via the CPB oxygenator 103. The operator may select the flow rate to the oxygenator 103 by using flow control valve 139. This effectively controls the rate that carbon dioxide is flushed from patient's blood into the apparatus and hence provides some control as to the relative acidity or alkalinity of the patient 107.

Carbon dioxide is absorbed by primary carbon dioxide absorber 135 and the reduction in the oxygen level is detected by fuel cell sensor 131 triggering, via the high gain circuit, replenishment of oxygen levels under the control of oxygen MFC 129.

Xenon sensor 143 measures the xenon concentration in the main circuit 102. This reading may be compared to other readings to reach various conclusions. For example, if the oxygen concentration measured by oxygen fuel cell sensor 131 does not equal 100 minus the xenon concentration measured by xenon sensor 143, it is indicative of contamination, for example by carbon dioxide or nitrogen, and the operator may be alerted to vent the apparatus to atmosphere or recover the used gas. Alternatively, this may be done automatically at a preset level. The xenon sensor 143 is also used to monitor the xenon concentration predicted from the level of the bellows. Similarly, if these two readings do not agree, this may be indicative of too much carbon dioxide, nitrogen or oxygen. As a result, the operator may again choose to vent to atmosphere or recover the used gas.

If the gas volume in the apparatus is increased, the level of bellows 145 increases. If the level of bellows 145 exceeds a preset level, gas is vented from the apparatus, again either manually or automatically, via atmospheric vent 157 and/or xenon recovery valve 153. Optionally, the sensor 146 may be connected to ultrasonic analyser 143 so that when the bellows 145 upper level is exceeded, vent 157 or valve 153 is selectively opened depending on the xenon content of the gas measured by analyser 143.

Referring now to Figure 2, a ventilator circuit generally designated 200 is connected at the filters 115 of the apparatus of Figure 1 to replace the CPB circuit. Fresh gas passes through the outlet filter 115 (see Figure 1) into the ventilator circuit 200 via a check valve 213 to provide gas to the ventilator thereby maintaining the oxygen and xenon concentrations in the ventilator circuit 200 at the required levels.

The ventilator circuit 200 includes a conventional ventilator 201 of the kind providing a positive drive gas pressure (above atmospheric pressure) in pulses for a second or two, followed by a slightly longer period at atmospheric pressure. The period, cycle time and power of the drive gas pressure is set, in conventional manner, to match the needs of the patient 205.

When the ventilator drive pressure is positive, it pushes gas out of the bellows of a bellows assembly 202 via a control valve 203 and a check valve 204 into the lungs of the patient 205. Valve 203 is a pneumatically operated valve that is held closed by the positive ventilator drive pressure during the inflation of the patient's lungs. When the ventilator 201 proceeds to the atmospheric pressure part of its cycle, which allows the patient's lung to relax and deflate, exhaled gas (oxygen removed, carbon dioxide added) flows from the lungs via a check valve 209 to a soda-lime

absorber canister 210. The canister 210 absorbs carbon dioxide from the exhaled gas and then allows it to flow back to refill the bellows of the bellows assembly 202. This gas may then be pumped back to the patient's lungs by the bellows during the next positive pressure pulse from the ventilator 201. The level of carbon dioxide in the gas from the patient's lungs is measured continuously by a CO_2 analyser 207, which monitors both the end-tidal (peak) CO_2 level, which gives an indication of the patient's correct respiration, and the minimum CO_2 level, which gives an indication of exhaustion of the soda-lime 210.

When the ventilator 201 is in the atmospheric pressure part of its cycle, the valve 203 is open and, if the bellows inside the bellows assembly 202 has reached the top of its travel and the gas pressure becomes positive enough (a few millibar), gas may flow from the bellows into an optional bag 211a, past an optional pressure relief valve 212a and back to the gas recycling circuit 102 (see Figure 1) via an outlet 208 and filter 115 (see Figure 1). The bag 211a and optional pressure relief valve 212a are needed if the tubing connecting the recycling circuit 102 to the ventilator circuit 200 are not large enough to assure correct operation of the bellows pressure relief via valve 203. In an alternative arrangement, the bag 211b and relief valve 212b are located upstream of the check valve 203.

Figure 3 shows an alternative ventilator circuit 300 for connection to gas recycling circuit 102 of Figure 1 in corresponding manner to the ventilator circuit 200 of Figure 2. It is specially designed to ensure that the patient 305 receives fresh gas from the recycling circuit 102 of Figure 1 and that the exhaled gas is not mixed with fresh gas but is fed back to the recycling circuit 102.

Fresh gas from the outlet filter 115 (see Figure 1) is fed to the ventilator circuit 300 at inlet 301. An optional

feed bellows assembly 302 is connected downstream of the inlet and has a weight 303 to ensure that it runs at a small positive pressure, which is sufficient to feed gas through a check valve 304 to raise the bellows in a ventilator bellows assembly 305 when the drive gas pressure from ventilator 306 is atmospheric.

The ventilator 306 and bellows assembly 305 function in a similar way to that normally employed in prior art ventilator systems. Periodically, ventilator 306 applies positive (above atmospheric) gas pressure to the outside of the bellows in the bellows assembly 305, collapsing the bellows and forcing gas from inside the bellows through a check valve 307 to the lungs of the patient 308. The ventilator drive gas to the bellows is also applied to a pneumatically operated valve 309 to close it, so that all the gas from the bellows assembly 305 goes to the patient 308.

When the gas pressure from the ventilator 306 is relaxed back to atmospheric pressure, the bellows in bellows assembly 305 re-inflates with fresh gas from the inlet 301 and the feed bellows 302. The check valve 307 is biased with a spring or weight so that it only opens at a few millibar, assuring that 100% of fresh gas flows into the bellows assembly 305.

Simultaneously with the refill of the main bellows assembly 305 the patient's lungs relax, exhaling gas containing less oxygen and more carbon dioxide relative to fresh gas. The exhaled gas flows through pneumatically operated valve 309, which is now open to the gas return circuit (since the drive gas pressure is atmospheric). The gas return circuit may optionally include a variable gas volume comprising an additional bellows or flexible bag 310.

CLAIMS

1. Apparatus comprising:-

a medical device requiring a supply of a gaseous composition comprising a first gas and a second gas;

a main circuit for recirculating gas through the medical device and comprising:-

a circulation pump for pumping gas through the main circuit,

a gas outlet connected to the medical device,

a gas inlet connected to the medical device,

a first supply conduit for supply of gas of a first composition to the main circuit,

a second supply conduit for supply of gas of a second composition different from said first composition to the main circuit,

a first supply flow control means for controlling the flow of gas through the first supply conduit, and

a second supply flow control means for controlling the flow of gas through the second supply conduit;

a concentration determining means for determining the concentration of at least one gas of the gaseous composition within the main circuit; and

a means for venting gas from the main circuit.

2. Apparatus as claimed in Claim 1, which further comprises a bypass circuit, which permits at least a portion of the recirculating gas to bypass the gas outlet, the medical device and the gas inlet, and a gas outlet flow control means for controlling the flow of gas through the gas outlet.

3. Apparatus as claimed in Claim 2, which further

comprises a pressure maintaining means for maintaining the pressure to the gas outlet by controlling the flow of gas through the bypass conduit whereby flow of gas through the bypass conduit is prevented unless a predetermined pressure is attained.

4. Apparatus as claimed in Claim 2 or Claim 3, which further comprises a circuit volume regulating means for taking up temporary increases in recirculating gas volume and compensating for temporary decreases in recirculating gas volume.

5. Apparatus as claimed in Claim 4, wherein the circuit volume regulating means comprises expansion bellows.

6. Apparatus as claimed in Claim 4 or Claim 5, which further comprises a monitoring means for monitoring the relative increases and decreases in gas volume in the circuit according to the circuit volume regulating means.

7. Apparatus as claimed in any one of the preceding claims comprising a first circuit gas concentration controlling means, including the first supply flow control means, for controlling the concentration of the first gas in the gaseous composition and a second circuit gas concentration controlling means, including the second supply flow control means, for controlling the concentration of the second gas in the gaseous composition.

8. Apparatus as claimed in Claim 7, wherein the first circuit gas concentration controlling means comprises a first gas concentration determining means for determining the concentration of the first gas in the gaseous composition and communicating with the first supply flow control means for controlling flow of the first gas through the first supply conduit and the second circuit gas concentration controlling means comprises a second gas

concentration determining means for determining the concentration of the second gas in the gaseous composition and communicating with the second supply flow control means for controlling flow of the second gas through the second supply conduit, whereby on reaching a respective predetermined level, each of said determining means triggers the corresponding flow control means to increase the flow of the corresponding gas to the circuit.

9. Apparatus as claimed in Claim 7, wherein the first circuit gas concentration controlling means comprises a first gas concentration determining means for determining the concentration of the first gas in the gaseous composition and communicating with the first supply flow control means for controlling flow of the first gas through the first supply conduit and the second circuit gas concentration controlling means comprises a monitoring means for monitoring the relative increases and decreases in gas volume in the circuit and communicating with the second supply flow control means for controlling flow of the second gas through the second supply conduit, whereby on reaching a respective predetermined level, each of said determining means and said monitoring means triggers the corresponding flow control means to increase the flow of the corresponding gas to the circuit.

10. Apparatus as claimed in Claim 8 or Claim 9, wherein the first circuit gas concentration controlling means comprises a relatively high gain analog electrical circuit and the second circuit gas concentration controlling means comprises a relatively low gain analog electrical circuit, whereby the increase in flow rate of the first gas is relatively quick and the increase in flow rate of the second gas is relatively slow.

11. Apparatus as claimed in any one of the preceding claims wherein the medical device is selected from a

cardiopulmonary bypass oxygenator and an artificial ventilator.

12. Apparatus as claimed in Claim 11, wherein the medical device is a cardiopulmonary bypass oxygenator.

13. Apparatus as claimed in any one of the preceding claims, which further comprises an ultrasonic xenon analyser.

14. Apparatus as claimed in any one of the preceding claims, comprising a gas recovery space and a vent for feeding recirculating gas to said space.

15. Apparatus as claimed in Claim 14, wherein the gas recovery space is an ullage space of a container providing said first composition.

16. Apparatus as claimed in any one of Claims 12 to 15, wherein the medical device is a cardiopulmonary bypass oxygenator and said apparatus further comprises one or more of a carbon dioxide absorber, a carbon dioxide analyser and a pressure relief device downstream from the oxygenator.

17. An apparatus for providing and circulating a gaseous composition to a medical device, said apparatus comprising:-

a main circuit for recirculating gas to the medical device and comprising:-

a circulation pump for pumping gas through the circuit to supply the medical device with a gas composition comprising a first gas and a second gas,

a gas outlet for connection to the medical device to supply gas thereto,

a gas inlet for connection to the medical device to receive spent gas therefrom,

a first supply conduit for supply of gas of a

first composition to the circuit,

a second supply conduit for supply of gas of a second composition different from said first composition to the circuit,

a first supply flow control means for controlling the flow of gas through the first supply conduit, and

a second supply flow control means for controlling the flow of gas through the second supply conduit;

a concentration determining means for determining the concentration of at least one gas in the gaseous composition within the circuit; and

a means for venting gas from the circuit.

18. Apparatus as claimed in Claim 17, which further comprises a bypass circuit, which permits at least a portion of the recirculating gas to bypass the gas outlet and the gas inlet, and a gas outlet flow control means for controlling the flow of gas through the gas outlet.

19. Apparatus as claimed in Claim 18, which further comprises a pressure maintaining means for maintaining the pressure to the gas outlet by controlling the flow of gas through the bypass conduit whereby flow of gas through the bypass conduit is prevented unless a predetermined pressure is attained.

20. Apparatus as claimed in Claim 18 or Claim 19, which further comprises a circuit volume regulating means for taking up temporary increases in recirculating gas volume and compensating for temporary decreases in recirculating gas volume.

21. Apparatus as claimed in Claim 20, wherein the circuit volume regulating means comprises expansion bellows.

22. Apparatus as claimed in Claim 20 or Claim 21, which further comprises a monitoring means for monitoring the relative increases and decreases in gas volume in the circuit according to the circuit volume regulating means.

23. Apparatus as claimed in any one of Claims 17 to 22 comprising a first circuit gas concentration controlling means, including the first supply flow control means, for controlling the concentration of the first gas in the gaseous composition and a second circuit gas concentration controlling means, including the second supply flow control means, for controlling the concentration of the second gas in the gaseous composition.

24. Apparatus as claimed in Claim 23, wherein the first circuit gas concentration controlling means comprises a first gas concentration determining means for determining the concentration of the first gas in the gaseous composition and communicating with the first supply flow control means for controlling flow of the first gas through the first supply conduit and the second circuit gas concentration controlling means comprises a second gas concentration determining means for determining the concentration of the second gas in the gaseous composition and communicating with the second supply flow control means for controlling flow of the second gas through the second supply conduit, whereby on reaching a respective predetermined level, each of said determining means triggers the corresponding flow control means to increase the flow of the corresponding gas to the circuit.

25. Apparatus as claimed in Claim 23, wherein the first circuit gas concentration controlling means comprises a first gas concentration determining means for determining the concentration of the first gas in the gaseous composition and communicating with the first supply flow control means for controlling flow of the first gas through

the first supply conduit and the second circuit gas concentration controlling means comprises a monitoring means for monitoring the relative increases and decreases in gas volume in the circuit and communicating with the second supply flow control means for controlling flow of the second gas through the second supply conduit, whereby on reaching a respective predetermined level, each of said determining means and said monitoring means triggers the corresponding flow control means to increase the flow of the corresponding gas to the circuit.

26. Apparatus as claimed in Claim 24 or Claim 25, wherein the first circuit gas concentration controlling means comprises a relatively high gain analog electrical circuit and the second circuit gas concentration controlling means comprises a relatively low gain analog electrical circuit, whereby the increase in flow rate of the first gas is relatively quick and the increase in flow rate of the second gas is relatively slow.

27. Apparatus as claimed in any one of Claims 17 to 26, which further comprises an ultrasonic xenon analyser.

28. Apparatus as claimed in any one of Claims 17 to 27, comprising a gas recovery space and a vent for feeding recirculating gas to said space.

29. Apparatus as claimed in Claim 28, wherein the gas recovery space is an ullage space of a container providing said first composition.

30. A method of providing a medical device with a gaseous composition comprising a first gas and a second gas, said method comprising:-

feeding a gaseous composition of a desired composition to the medical device;

collecting spent gas mixture from the device;

determining the concentration of each of the components of the gaseous composition remaining in the spent gas mixture;

processing the spent gas mixture to remove unwanted components;

replenishing components in the spent gas mixture in response to the concentration determination to regenerate said desired composition; and

recirculating resultant gaseous composition to the medical device.

31. A method as claimed in Claim 30, which further comprises maintaining the pressure of the gaseous composition being fed into the medical device at a desired level by diverting a portion of the gaseous composition to bypass the medical device when the desired pressure is exceeded.

32. A method as claimed in Claim 30 or Claim 31, which further comprises removing and storing spent gas for subsequent recovery in response to the concentration of an active component falling below a predetermined level or the concentration of an unwanted component exceeding a predetermined level.

33. A method as claimed in any one of Claims 30 to 32, wherein the medical device is a cardiopulmonary bypass oxygenator or an artificial ventilator.

34. A method as claimed in any one of Claims 30 to 33, wherein the first gas is oxygen and the second gas comprises

xenon.

35. A method as claimed in Claim 34, wherein the second gas is a mixture of xenon and oxygen.

36. A method as claimed in Claim 35, wherein the second gas is a mixture of xenon and oxygen in the ratio of about 80% to about 20% by volume.

37. A method for the extracorporeal treatment of blood by contacting blood with a recirculating gaseous composition in a device provided with a gaseous composition using a method defined in any one of Claims 30 to 36.

38. An apparatus as claimed in Claim 1, substantially as hereinbefore described with reference to the drawing.

39. An apparatus as claimed in Claim 17, substantially as hereinbefore described with reference to the drawing.

40. A method as claimed in Claim 30, substantially as hereinbefore described with reference to the drawing.

41. A method as claimed in Claim 37, substantially as hereinbefore described with reference to the drawing.

ABSTRACT

Medical Gas Recirculation System

A gas mixture (102) is recirculated through a medical device (103) by collecting (113) spent gas mixture from the device; determining (131) the concentration of each of the components of the gaseous composition remaining in the spent gas mixture; processing (135, 133) the spent gas mixture to remove unwanted components; replenishing (123, 129) components in the spent gas mixture in response to the concentration determination step to regenerate said desired composition; and recirculating (105) the resultant gaseous composition to the medical device (103). Preferably, flow to the device is maintained constant by causing a portion of the gas mixture to bypass the device when the gas mixture pressure exceeds a predetermined level. The method has particular application to the feed of a binary oxygen/xenon mixture to a cardiopulmonary bypass oxygenator or an artificial ventilator.

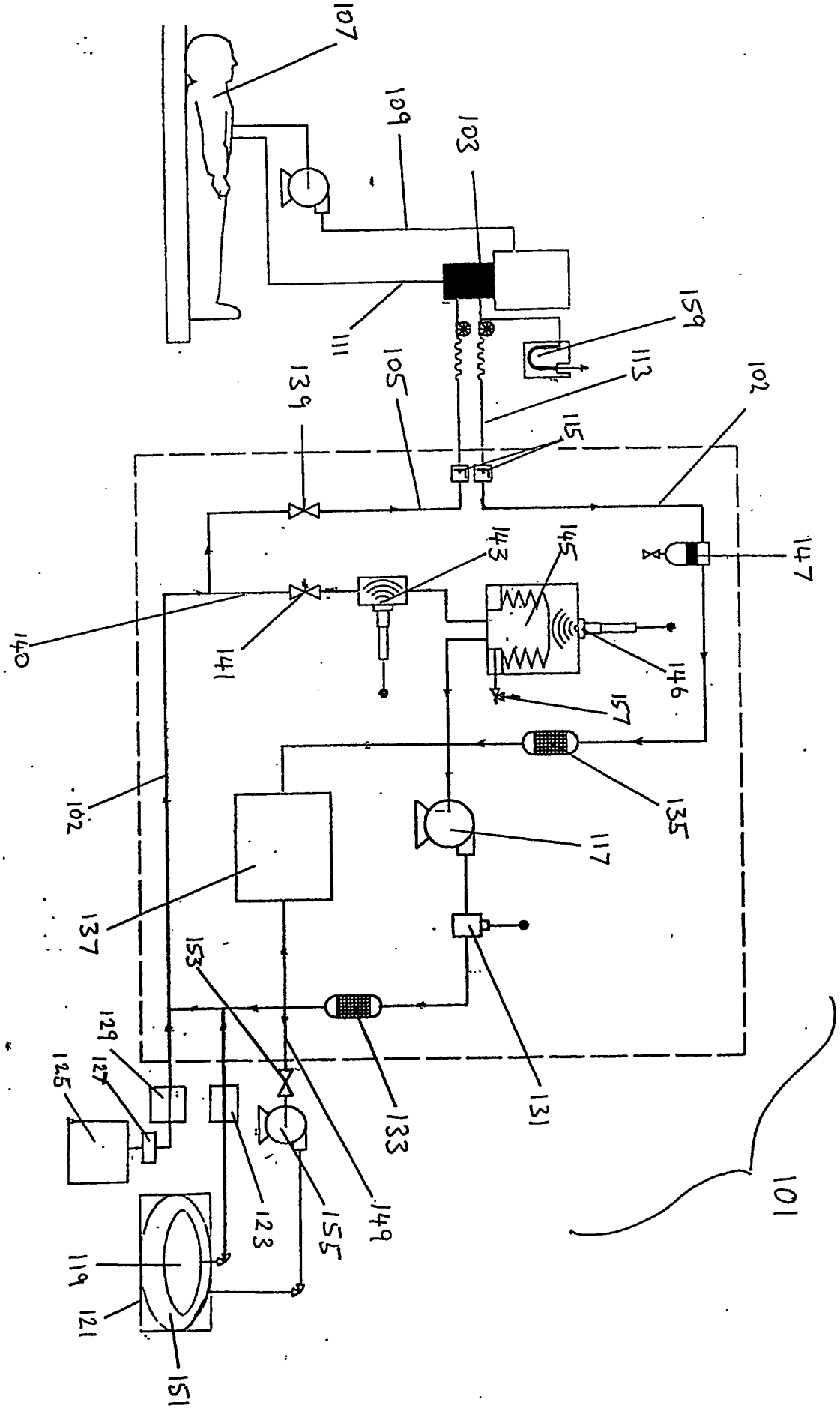
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FIGURE 1

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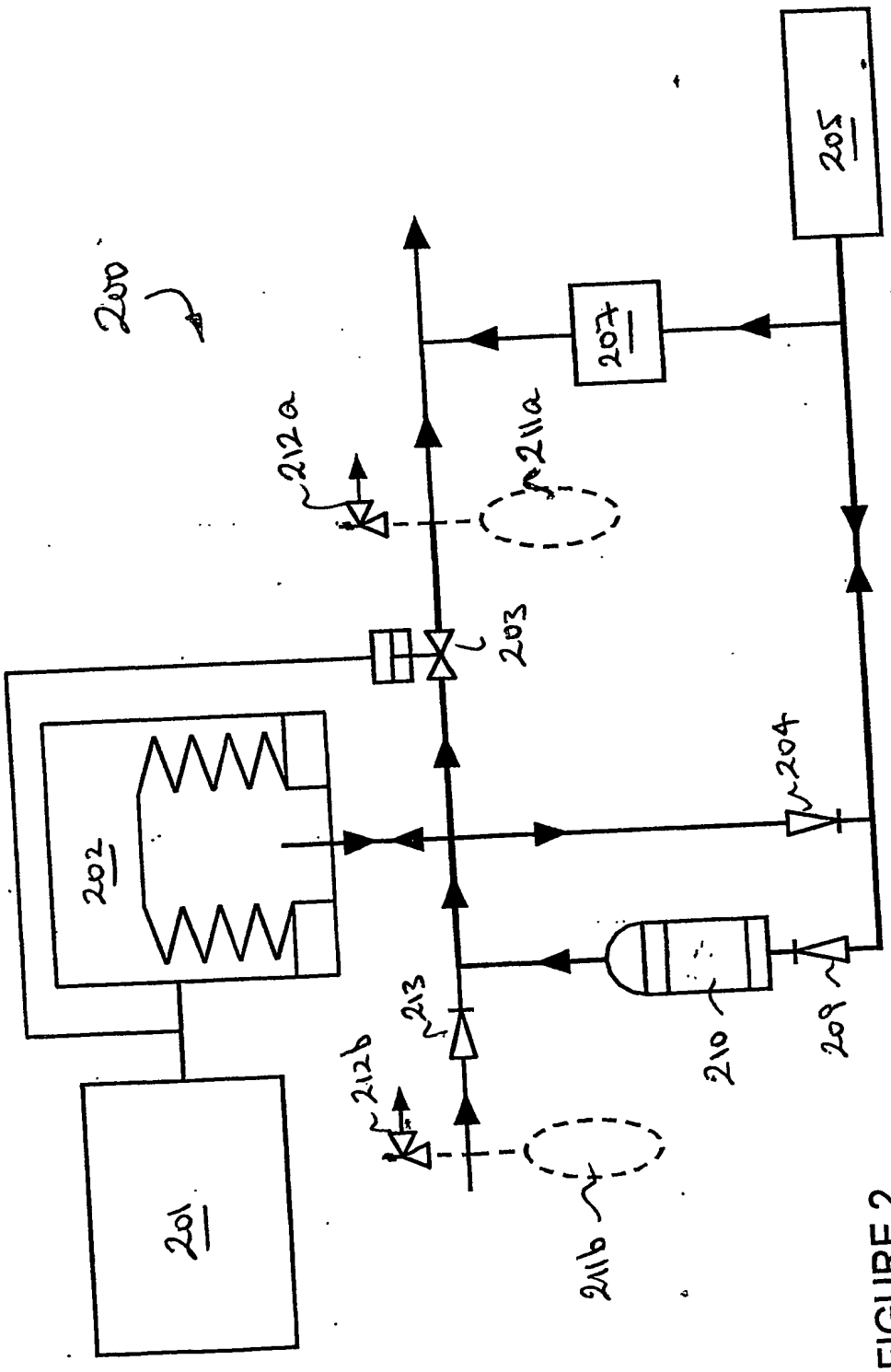

FIGURE 2

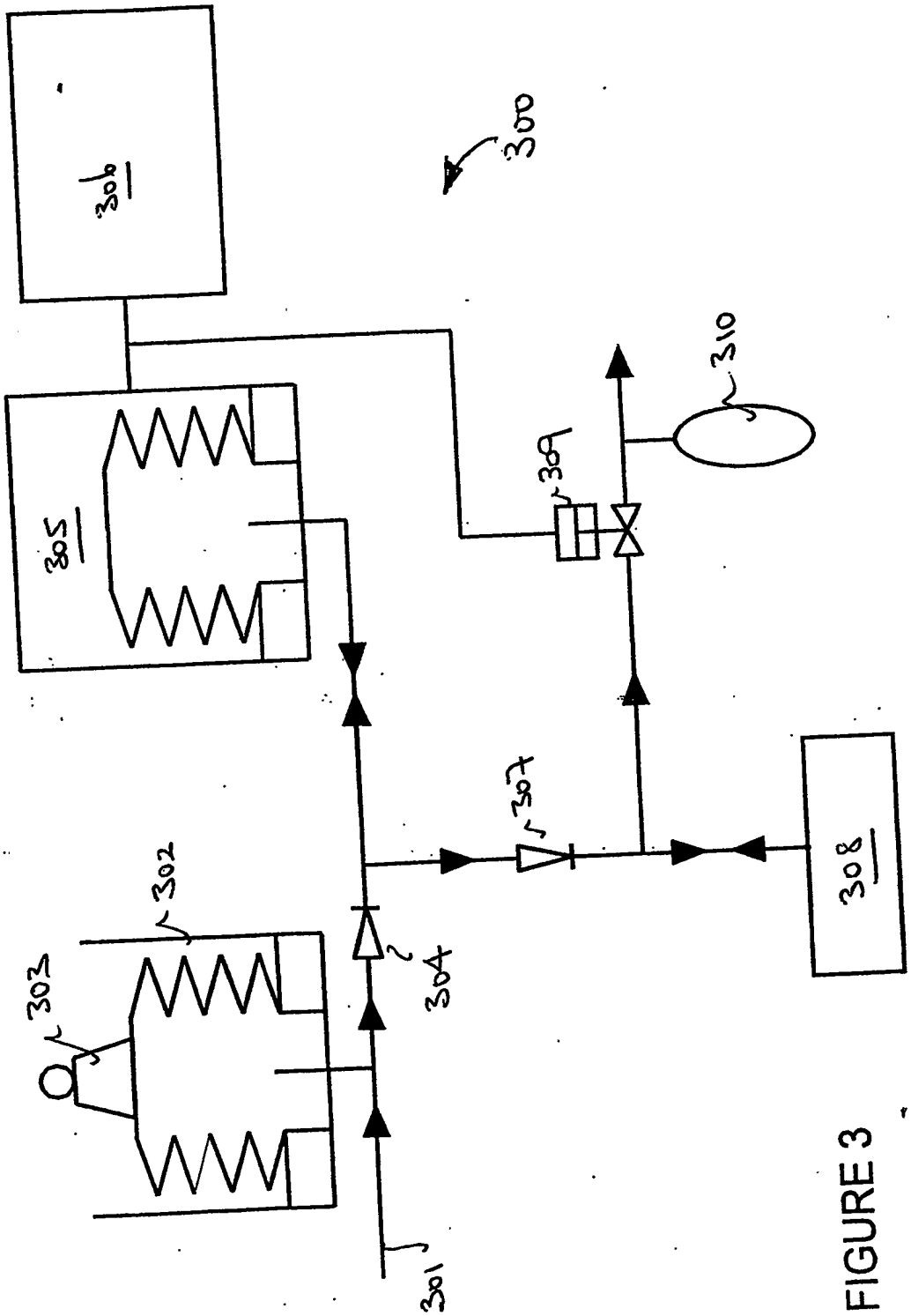

FIGURE 3